

**REMARKS**

Reconsideration is requested.

Claims 1-15 and 18-19 have been cancelled, without prejudice.

Upon entry of the above amendments, claims 16-17 and 20-43 will be pending.

The applicants again request a Decision on the Petition filed July 14, 2004. The Examiner is requested to issue a new non-final Office Action in the event the present Amendments are not believed by the Examiner to place the application in condition for allowance. The new non-final Office Action is requested to allow the Patent Office time to render a Decision on the Petition filed over seven (7) months ago without requiring the applicants to pay further extension fees. The Patent Office continued delay in rendering a Decision on the Petition filed July 14, 2004 continues to unfairly require extension fees of the applicants so long as prosecution is closed. Issuance of a non-final Office Action and re-opening prosecution will at least allow the Patent Office to continue in its delay in rendering a Decision without requiring further extension fees from the applicants.

The applicants again note in this regard, as submitted in the Request of November 2, 2004, that while the Examiner has indicated in the Office Action of October 15, 2004 that claims 17 and 20-26 have been rejoined and examined with the previously-considered subject matter, as requested in the Petition, the subject matter of claims 41 and 42 continues to be withdrawn from consideration. The Examiner has not responded to the applicants Petition in this regard and the applicants have not received a Decision from the Patent Office on the Petition with regard to claims 41 and 42. See, pages 5-6 for example of the Petition.

Entry of the above amendments is requested as, at a minimum, the amendments place the application in better condition for appeal by at least reducing issues for appeal, as noted further below.

Rejoinder and allowance of the previously-withdrawn method claims, and allowance with the product claims from which they depend, are requested.

The claims, including the withdrawn claims, have been amended pursuant to the format provided in the USPTO "flyer" - REVISED AMENDMENT PRACTICE: 37 CFR 1.121 CHANGED COMPLIANCE IS MANDATORY - Effective Date: July 30, 2003 (Rev.3 (07/24/03)). See, for example, Claims 7 and 8 of the Examples on page 2 of the "flyer".

The Examiner's comments with regard to the specification stated on pages 2-3 of the Office Action dated October 19, 2004 are not understood. There is no specific objection or rejection of the specification or claims stated in ¶¶ 1 and 2 of the Office Action.

The Examiner is again urged to appreciate however that the recited "E1s" has been described throughout the current specification, was known in the art prior as of the applicants' earliest claimed priority application and is moreover cited at least once in each of the priority documents and provisional applications. Specifically, the Examiner is requested to see, for example, Table 1, on page 29 of U.S. Patent application publication No. 2003/0118603 (publication of the current application) which describes "E1s" on at least 6 occasions; Example 15, ¶[0524] of U.S. Patent application publication No. 2003/0118603 states "The HCV E1s protein (amino acids 192-326)", and Examples 12 and 13 of U.S. Patent application publication No. 2003/0118603

which describe in paragraphs [0508] and [0515], respectively, "...with E1 (aa 192-326)" and further refer to Table 2 of WO 99/67285. The heading of Table 2 of WO 99/67285 (copy enclosed herewith and listed separately on the attached PTO 1449 Form) is "The E1s vaccine sequence aligned with...". Moreover, Example 18 of U.S. Patent application publication No. 2003/0118603 describes, in paragraph [0542], overlapping 20-mer peptides "covering the entire sequence of E1s".

For completeness, the applicants note that the term "E1s" is described in WO 99/67285 (which was filed as PCT/EP99/04342, priority of which is claimed in the present application), and more specifically on page 3, line 11 and in Example 1. These explanations were also present in the two EP priority applications EP 98 870 142.1 (page 3, line 7 and Example 1) and EP 99 870 033.0 (page 3, line 9 and Example 1)

The Table below further indicates, for example, in the applicants view, the description of the term "E1s" in the different documents:

	US 6,150,134	EP 98 870 142.1	EP 99 870 033.0	PCT/EP99/04342
Table 1	√			
Example 12		√ (as Example 4)	√ (as Example 4)	√ (as Example 4)
Example 13		√ (as Example 5)	√ (as Example 5)	√ (as Example 5)
Example 18				

	US 60/304,194	US 60/260,669	US 60/315,768
Table 1	√	√	√
Example 12		√	√
Example 13		√	√
Example 18			√

The term E1s is described throughout the present application, the claimed priority applications and was well known in the art.

Moreover, support for the presently claimed invention may be found throughout the present and priority applications. Specifically, support in EP 98 870 142.1, may be

found, for example, at page 3, lines 4-13 and Examples 4-6 as well as Table 3; support in EP 99 870 033.0 may be found, for example, at page 3, lines 6-15 and Examples 4-6, as well as Table 3; support in PCT/EP99/04342 may be found, for example, at page 3, lines 7-17 and Examples 4-6, as well as Table 3; support in US application Serial No. 60/304,194 may be found, for example, in Example 11 and the claims; support in US application Serial No. 60/260,669 may be found, for example, in Examples 11-16 and the claims; and support in US application Serial No. 60/315,768 may be found, for example, in the Examples 11-18 and the claims. The pending claims are supported by the priority documents and the Examiner is requested to specifically accord benefit of the priority filing dates.

The above comments were previously presented and the Examiner has not provided any response thereto or even indicated that the previously-submitted comments have been considered.

Consideration of the above and previous comments in this regard is requested. The Examiner is requested to clearly articulate any specific objection or rejection based on the Examiner's belief that the specification fails to describe E1s proteins.

To the extent not obviated by the above amendments, the Section 112, second paragraph, rejection of claims 15, 16-17, 20-26, 36-39, 40 and 43, is traversed. Reconsideration and withdrawal of the rejection is requested.

Claim 15 has been canceled, without prejudice, above such that the basis for the rejection stated in ¶¶1-4 on page 3 of the Office action dated October 19, 2004, is moot. The Examiner's reference to 37 CFR § 1.111(c) on page 3 in ¶13 of the Office Action is not understood and clarification is requested in the event

the Examiner continues to believe reliance on the same is appropriate in rejecting the applicants claims and/or previous remarks. Specifically, the applicants indicated how they believed their claimed invention defined a patentable invention on page 15, last paragraph of their Amendment of July 14, 2004.

As for the Examiner's continued objection to the recited "part thereof", the only reason provided by the Examiner for maintaining the rejection is because the applicants allegedly failed to comply with 37 CFR § 1.111(c). See, page 3, ¶15 of the Office Action dated October 19, 2004. The Examiner is requested to see however page 16, first paragraph of the applicants Amendment of July 14, 2004 which responded completely to the Examiner's rejection. Moreover, the purpose of the applicants needing to respond to an indefiniteness rejection, under Section 112, second paragraph, by pointing out the patentable novelty of the claimed invention, as apparently required by the Examiner, is unclear to the applicants. That is, the applicants believe that arguments regarding the novelty of the claimed invention are best made in response to rejections made under 35 USC § 102, as opposed to 35 USC § 112, second paragraph.

Reconsideration and withdrawal of the Section 112, second paragraph, rejection are requested.

The Examiner is requested to hold the obviousness-type double patenting rejection of claims 15, 16, 17, 18, 21-26 and 36-39 over claims 13, 16 and 21 of U.S. Patent No. 6,635,257, and the provisional obviousness-type double patenting rejection

of claims 15, 16, 18, 21-26, 36-39 and 40 over claims 1, 2, 3, 5, 7, 9, 10, 11, 12, 13 and 14 of application Serial No. 09/995,791, in abeyance until such time as allowable subject matter is identified, at which time the applicants will consider whether filing a Terminal Disclaimer is appropriate.

The Section 102 rejection of claims 15, 16, 17, 20-26, 36-39, 40 and 43 over WO96/04385A2, is traversed. Withdrawal of the rejection is requested in view of the following distinguishing comments.

Initially, the applicants note that the new final rejection of claim 17 over WO96/04385A2 is a new rejection necessitated by the applicants Amendment of July 14, 2004. The finality of the Office Action dated October 19, 2004 should be withdrawn and a new non-final Action mailed in the event the Examiner believes claim 17 is unpatentable over the art. Claim 17 was not amended in the Amendment of July 14, 2004.

Moreover, claims 16 and 17, and claims dependent there from, are submitted to be patentable over WO96/04385A2 as the U.S. Patent Office has consistently stated during the U.S. prosecution of the U.S. national phase of PCT/EP95/03031 (which published as WO96/04385A2), i.e., Serial No. 08/928,757, that the disclosure of WO96/04385A2 failed to provide an enabling disclosure for a vaccine of the sort being presently claimed. See, for example, the Office Actions dated July 2, 1999 (rejection of claims 49-51, 53 and 55-56 for example), February 24, 2000 (rejection of claims 49-51, 53 and 55-56 for example), and November 15, 2000 (rejection of claims 49-51, 53 and 55-56 for example). As noted in the Remarks of the Amendment dated July 14, 2004, an alleged non-enabling disclosure can not be an anticipatory reference. As the Patent

Office has previously indicated that the disclosure of Serial No. 08/928,757 allegedly fails to enable a vaccine composition, the Patent Office cannot rightfully now hold that the same disclosure can be an anticipation of a vaccine claim.

Withdrawal of the Section 102 rejection based on WO96/04385A2 is requested.

The Section 102 rejection of claims 15, 16, 18 and 36 over Choo (PNAS 1994, vol 91, pp 1294-1298) will be moot upon entry of the above amendments. The Examiner's indication that the subject matter of claim 17 is patentable over Choo is acknowledged, with appreciation. Claim 16 is further submitted to be patentable over Choo as the reference is not believed to teach each and every aspect of the claimed invention. Entry of the above and withdrawal of the Section 102 rejection over Choo are requested.

The Section 102 rejection of claims 15, 16, 18 and 36 over Houghton et al (Prospects for prophylactic and therapeutic hepatitis C virus vaccines. Princess Takamatsa Symp. 1995, vol 25, pp 237-243) will be moot upon entry of the above amendments. The Examiner's indication that the subject matter of claim 17 is patentable over Houghton is acknowledged, with appreciation. Claim 16 is further submitted to be patentable over Houghton et al as the reference is not believed to teach each and every aspect of the claimed invention. Entry of the above and withdrawal of the Section 102 rejection over Houghton are requested.

The Section 102 rejection of claims 15, 16, 18 and 36 over Houghton et al (Proceedings of IX Triennial International Symposium on Viral Hepatitis and Liver Disease, Rizettp Purcell, Gerin, Verme, eds., Edizioni Minerva Medica, Italy, 1997, pp. 656-657) will be moot upon entry of the above amendments. The Examiner's indication

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Serial No. 09/995,860  
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that the subject matter of claim 17 is patentable over Houghton is acknowledged, with appreciation. Claim 16 is further submitted to be patentable over Houghton et al as the reference is not believed to teach each and every aspect of the claimed invention. Entry of the above and withdrawal of the Section 102 rejection over Houghton are requested.

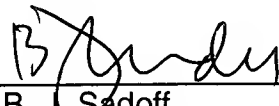
The Section 102 rejection of claims 15, 16, 18, 36 and 40 over Weiner (U.S. Patent No. 5,670,152) will be moot upon entry of the above amendments. The Examiner's indication that the subject matter of claim 17 is patentable over Houghton is acknowledged, with appreciation. Claim 16 is further submitted to be patentable over Weiner as the reference is not believed to teach each and every aspect of the claimed invention. Entry of the above and withdrawal of the Section 102 rejection over Houghton are requested.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested. The Examiner is requested to contact the undersigned in the event anything further is required.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

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